Remarks

Applicants respectfully bring to the Examiner's attention that a shortened statutory period of 1 month (not less than 30 days) was improper. Under MPEP §710.02(b) a shortened statutory period of 1 month (not be less than 30 days) should apply to:

(A) Requirements for Restriction Requirement or election of species only (no action on the merits) . . . MPEP §809.02(a) and §817; or

(B) When a reply by an applicant for a non-final Office Action is bona fide but includes an inadvertent omission, the examiner may set a 1 month shortened statutory time period to correct the omission . . . MPEP §710.01 and §714.03.

The Office Action mailed October 12, 2007 rejected the pending claims under 35 U.S.C. §103. A rejection under 35 U.S.C. §103 requires an action on the merits and a 3 month period would be proper to respond.

Accordingly, Applicants respectfully request that a three-month period to respond be applied to this case to which a response was due November 12, 2007 and a petition for a 2-month extension of time extending the response due date to March 12, 2008 would be proper.

Rejection under 35 U.S.C. §103

In response to the Official Action mailed October 12, 2007, Applicants have amended claim 1. Claims 3-6 have been withdrawn in response to a Restriction Requirement made August 10, 2007, as being drawn to a non-elected subject matter.

Claims 1 and 2 are rejected under 35 U.S.C. 103 as being unpatentable over Burns (Eur J. Endocrinol 146, 707, 2002) and as being unpatentable over Albert (US 2005/0014686). Applicats respectfully traverse.

The claims are limited to 4-5 cyclization (i.e. cyclisation of compound II). The prior art discloses 5-6 cyclization using an azide reagent which causes enormous technical problems in large amounts. However, use of more convenient cyclization agents failed for 5-6 cyclization. Surprisingly, it has been found that when amino acids 4-5 are cyclized, safer and convenient cyclization agents can be used such as HOBT and HBTU and give in good yields and excellent purity. This is clearly unexpected and could not be predicted from the cited prior art.

The yields obtained for the cyclised peptide is 77% for the process step connecting amino acids 4 and 5; the product having 84% purity and no detectable epimerized by-product (see Example 3, HBTU method b)).

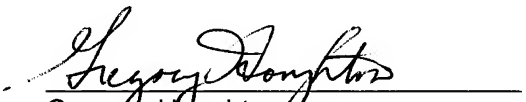
In contrast, under the same reaction conditions the process step connecting amino acids 5 and 6 yielded less than 20% cyclised peptide with only about 16% purity measured by HPLC. Such a crude product cannot be purified on a technical scale with reasonable effort.

There was no hint in the prior art as to how to modify the manufacturing process for making compounds of formula I on larger scale by avoiding critical reagents and obtaining the product in good yields and with high purity.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. 103 be withdrawn.

Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,



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Date: March 5, 2008